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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0474]

International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products; Draft Guidance for Industry on "Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish a Microbiological Acceptable Daily Intake;" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for comments of a draft guidance document for industry (#159) entitled "Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish a Microbiological ADI" (VICH GL–36). This draft guidance has been developed for veterinary use by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft VICH guidance document provides guidance for assessing the human food safety of residues from veterinary antimicrobial drugs with regard to effects on the human intestinal flora.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 30 days after date of publication in the* **Federal Register**] to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time.

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ADDRESSES: Submit written requests for single copies of the draft guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* Comments should be identified with the full title of the draft guidance and the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Louis T. Mulligan, Center for Veterinary Medicine (HFV–153), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6984, e-mail: *lmulliga@cvm.fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonization of Technical Requirements for Approval of Pharmaceuticals for

Human Use for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH steering committee is composed of member representatives from the European Commission, European Medicines Evaluation Agency, European Federation of Animal Health, Committee on Veterinary Medicinal Products, the United States' FDA, the U.S. Department of Agriculture, the Animal Health Institute, the Japanese Veterinary Pharmaceutical Association, the Japanese Association of Veterinary Biologics, and the Japanese Ministry of Agriculture, Forestry and Fisheries.

Four observers are eligible to participate in the VICH steering committee: One representative from the Government of Australia/New Zealand, one representative from the industry in Australia/ New Zealand, one representative from the Government of Canada, and one representative from the industry of Canada. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation for Animal Health (IFAH). An IFAH representative also participates in the VICH steering committee meetings.

II. Draft Guidance on Microbiological Acceptable Daily Intake (ADI)

The VICH steering committee held a meeting on May 8, 2003, and agreed that the draft guidance document entitled "Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish

a Microbiological ADI" (VICH GL–36) should be made available for public comment. This draft VICH guidance provides guidance for assessing the human food safety of residues from veterinary antimicrobial drugs with regard to effects on the human intestinal flora. The objectives of this guidance are as follows: (1) To outline the recommended steps in determining the need for establishing a microbiological ADI; (2) to recommend test systems and methods for determining no-observable adverse effect concentrations (NOAECs) and no-observable adverse effect levels (NOAELs) for the endpoints of health concern; and (3) to recommend a procedure to derive a microbiological ADI. It is recognized that different tests may be useful. The experience gained with the recommended tests may result in future modifications to this guidance and its recommendations.

FDA and the VICH Safety Working Group will consider comments about the draft guidance document. Information collection is covered under Office of Management and Budget (OMB) control number 0910–0032.

III. Significance of Guidance

This draft document, developed under the VICH process, has been revised to conform to FDA's good guidance practices regulation (21 CFR 10.115).

The draft VICH guidance (#159) is consistent with the agency's current thinking on the general approach to establish a microbiological ADI. This guidance does not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternative method may be used as long as it satisfies the requirements of applicable statutes and regulations.

IV. Comments

This draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit written or electronic comments regarding this draft guidance

document. Written comments should be submitted to the Division of Dockets Management (see **ADDRESSES**). Submit written or electronic comments by [*insert date 30 days after date of publication in the* **Federal Register**] to ensure adequate consideration in preparation of the final guidance. Two copies of any mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Electronic comments may also be submitted electronically on the Internet at *http://www.fda.gov/dockets/ecomments*. Once on this Internet site, select "[docket number] entitled 'Studies to evaluate the safety of residues of Veterinary Drugs in Human Food: General Approach to Establish a Microbiological ADI' (VICH GL–36)" and follow the directions.

Copies of the draft guidance document entitled "Studies to evaluate the safety of residues of Veterinary Drugs in Human Food: General Approach to Establish a Microbiological ADI" (VICH GL–36) may be obtained on the Internet from the CVM home page at *http://www.fda.gov/cvm*.

Dated: 10/31/03

October 31, 2003.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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